U.S. Consumer Product Safety Commission

LOG OF MEETING

SUBJECT: Meeting of the ASTM E56 Committee (Nanotechnology)

DATE OF MEETING: November 1-2, 2022

PLACE OF MEETING: Teleconference

LOG ENTRY SOURCE: Joanna Matheson (HSTR)

COMMISSION ATTENDEES: Joanna Matheson (HSTR)

NON-COMMISSION ATTENDEES: Contact ASTM for a complete list.

SUMMARY OF MEETING:

ASTM E56 focuses on standardization in the field of nanotechnologies, understanding and control of matter and processes at the nanoscale where the onset of size-dependent phenomena usually enables novel applications, as well as use of nanoscale materials to create improved materials, devices, and systems that exploit these new properties. Specific subcommittees address the development of standards and guides for terminology and nomenclature; education and outreach; physico-chemical characterization; nano-enabled consumer products; environmental health and safety; and nano-enabled medical products.

On Tuesday, November 1, 2022, through Wednesday, November 2, 2022, the ASTM E56 (nanotechnology) committee and subcommittees met in person and by teleconference. Staff participated in the executive committee meeting and subcommittee meetings for Terminology and Informatics (E56.01), Physical and Chemical characterization (E56.02), Environmental, Health and Safety (E56.03), Nano-enabled Consumer Products (E56.06), Education and Workforce Development (E56.07), and Nano-enabled Medical Products (E56.08).

During the executive committee meeting, a liaison report was provided on ISO TC/229 (nanotechnologies) activities, including liposome projects, and on a liposome stability

and reference material workshop held in September 2022. The workshop focus was to collect enough information to initiate the development of liposomal reference materials. Similarly, NIST and the European Union's Joint Research Centre (JRC) are forming an interest group to collaborate on lipid-based research. Participating in activities, particularly a new task force on nano- and micro-plastics, by the organization CCQM was also discussed during the Executive committee meeting. CCQM is responsible for developing, improving and documenting the equivalence of national standards (including certified reference materials and reference methods).

The chair of the subcommittee for Terminology and Informatics (E56.01) provided an update on the IUPAC nomenclature committee and on InChi. InChi has met several times over the past year and published a paper on their approach to have InChi machine readable, in one line that reflects nanomaterial form, composition, shape, and size. In addition to the nomenclature issue on whether materials absorbed to a nanomaterial (i.e., from media) are part of the nomenclature, member discussion indicated that the proposed nomenclature will not cover agglomerate and aggregated nanomaterials. There was a proposal to consider InChi as a potential ASTM standard on unique identifiers.

At the May 2022 meeting, the E56.02 subcommittee noted that reviews were needed for six test methods. Three of these methods were revised, balloted and two were approved, E2859 *Guide for size measurement of nanoparticles using atomic force microscopy* and E2834 *Guide for measurement of particle size distribution of nanomaterials in suspension by Nanoparticle Tracking Analysis (NTA).* Two methods were submitted for reapproval with no changes in July 2022, E2578 *Practice for calculation of mean sizes/diameters and standard deviations of particle size distributions* and E2865 *Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Nanosized Biological Materials.* The work item, led by NIST, on determining lipid nanoparticle size and concentration using multi-detector asymmetrical flow field-flow fractionation (AF4) was balloted and not approved. Many comments were received and there was insufficient time to address all comments. Feedback during this subcommittee meeting was given on specifying a value for accuracy of the method (i.e., 5%). An update was given on newly approved work item 83164 *Analysis of lipid nanoparticle size and concentration using multi-detector AF4*. A draft document may be available for review by Spring 2023.

Three projects (E2524, E2525, and E2526) were revised, submitted for ballot and approved. The lead for these three project reviews has additional work items that she clustered into nucleic acid nanoparticles and infusion reactions. Extensive discussion by the subcommittee occurred on a path forward for these work items, including gauging interest from professional organizations and societies. NIOSH staff will review E-2535, a guide for handling unbound engineered nanoscale particles in work settings, which is due for review. Work item 48313 will be withdrawn.

At the E56.06 meeting, it was noted that E3025, *Guide for tiered approach to detection and characterization of silver nanomaterials in textiles* was revised by Health Canada staff, comments addressed and balloted. The one negative vote will be withdrawn and the standard approved. Work continues on *Identification of Silver Nanomaterials on Surfaces of Textile Fibers using Scanning Electron Microscopy-Energy Dispersive X-ray Analysis (SEM-EDX)*. This method can provide information on both nanomaterial size and form, whereas other methods using ICP-MS cannot. New potential projects on nano- and microplastics were discussed. It was noted that these materials are potentially present in food packaging, air (e.g., from tire abrasion), and water.

Per subcommittee E56.07, there is a suite of 6 standards published that cover basic skill sets for the nanotechnology workforce. They are working on updating the ASTM webpage for education and workforce development with these standards.

During the E56.08 subcommittee meeting updates were provided on multiple liposomal formulation projects. More than 20 organizations are involved in the development of work item 75607, a standard guide for the characterization of encapsulation, extraction and analysis of RNA in lipid nanoparticles for drug delivery. The scope of the project was changed from mRNA to RNA lipid nanoparticles to reflect the current use siRNA, miRNA, mRNA, and saRNA lipid nanoparticles. Another new work item is a method that assess the activation of the complement system in human plasma. This is a joint project between NIST and the European Union's JRC. Potential projects for liposomal standards include determination of in vitro drug release, quantitation of lipid degradants in liposomal drug formulations, and quantitation of poly(ethylene glycol) coating on gold nanorod surfaces.

Upcoming meetings will be held in Denver (May 8, 2023 – May 9,2023), and Washington, DC (November 6, 2023 -November 7, 2023).